

Appl. No. 09/147,367
Amendment dated: March 22, 2005
Reply to OA of: September 22, 2004

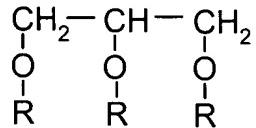
This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claims 1 - 141(canceled).

142(new). A method of enhancing an immune response to an antigen in a human or animal exposed to said antigen, the method comprising administering to the human or animal exposed to said antigen an immune response enhancing effective amount of an adjuvant consisting essentially of

i) a monoglyceride having a purity of at least 80%, the monoglyceride having the formula



wherein R is selected from H and an acyl group containing from 6 to 24 carbon atoms with the proviso that two of the R groups are H, and

ii) a fatty acid with 6 to 24 carbon atoms, the acyl group of the fatty acid being saturated or unsaturated, and

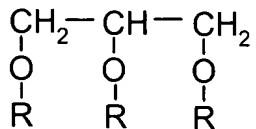
iii) water,

wherein the concentration of i) is from 0.1 g to 50 g per 100 ml of water, and the concentration of ii) is from 1 g to 50 g per 100 ml of water.

143(new). A method of enhancing an immune response to an antigen in a human or animal exposed to said antigen, the method comprising administering to the human or animal exposed to said antigen an immune response enhancing effective amount of an adjuvant consisting essentially of

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i) a monoglyceride having a purity of at least 80%, the monoglyceride having the formula



wherein R is selected from H and an acyl group containing from 6 to 24 carbon atoms with the proviso that two of the R groups are H;

ii) a fatty acid with 6 to 24 carbon atoms, the acyl group of the fatty acid being saturated or unsaturated; and

iii) water;

wherein the concentration of i) is from 0.1 g to 50 g per 100 ml of water, and the concentration of ii) is from 1 g to 50 g per 100 ml of water, with the proviso that the percent ratio of i) in ii) is between 10 to 90.

144(new). The method according to claim 142, wherein the purity of monoglyceride i) is at least 90%.

145(new). The method according to claim 142, wherein the purity of monoglyceride i) is at least 95%.

146(new). The method according to claim 142, wherein the acyl group of the monoglyceride i) contains from 8 to 20 carbon atoms.

147(new). The method according to claim 142, wherein the acyl group of the monoglyceride i) contains from 14 to 20 carbon atoms.

148(new). The method according to claim 142, wherein the acyl group of the fatty acid ii) contains from 8 to 20 carbon atoms.

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149(new). The method according to claim 142, wherein the acyl group of the fatty acid ii) contains from 14 to 20 carbon atoms.

150(new). The method according to claim 142, wherein the fatty acid ii) is selected from the group consisting of oleic acid, lauric acid, capric acid and caprylic acid.

151(new). A method of immunizing a human or animal, the method comprising administering to a human or animal a vaccine composition comprising an adjuvant as defined in claim 142, and an immunogenic quantity of an antigen component.

152(new). The method according to claim 151, wherein the antigen component is capable of causing the formation of an immune response in a human or animal including marine animals.

153(new). The method according to claim 151, wherein the antigen component is selected from the group consisting of antigens from pathogenic and non-pathogenic bacteria, viruses, parasites and tumor cells.

154(new). The method according to claim 151, containing, in 100 g of the final vaccine composition:

from 0.01 to 90 g of the antigen component

from 1 to 20 g of the monoglyceride i)

from 1 to 20 g of the fatty acid ii)

from 0.01 to 99 g of water

from 0.01 to 99 g of PBS or saline

and optionally one or more excipients.

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155(new). The method according to claim 154, wherein the vaccine composition comprises additional pharmaceutical excipients selected from the group consisting of preservatives, osmotic pressure controlling agents, pH-controlling agents, organic solvents, enzyme inhibitors, water absorbing polymers, absorption promoters and anti-oxidative agents.

156(new). The method according to claim 151, wherein the vaccine composition is in a form suitable for parenteral or mucosal administration.

157(new). The method according to claim 156, wherein the vaccine composition is in a form suitable for administration to the mucosa of the nose, mouth, vagina, rectum or intestine.

158(new). The method according to claim 156, wherein the vaccine composition is in a form suitable for administration to the mucosa of the nose.

159(new). The method according to claim 151, wherein the antigen component is selected from the group consisting of diphtheria toxoid, influenza virus, and rotavirus.

160(new). The method according to claim 151, wherein the content of monoglyceride i) of the adjuvant is at least 90%.

161(new). The method according to claim 151, wherein the content of monoglyceride i) of the adjuvant is at least 95%.

162(new). The method according to claim 151, wherein the acyl group of the monoglyceride i) of the adjuvant contains from 8 to 20 carbon atoms.

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163(new). The method according to claim 151, wherein the acyl group of the monoglyceride i) of the adjuvant contains from 14 to 20 carbon atoms.

164(new). The method according to claim 151, wherein the monoglyceride i) is selected from the group consisting of mono-olein, monomyristate, mono laurate and mono caprate.

165(new). The method according to claim 151, wherein the acyl group of the fatty acid ii) of the adjuvant contains from 8 to 20 carbon atoms.

166(new). The method according to claim 151, wherein the acyl group of the fatty acid ii) of the adjuvant contains from 14 to 20 carbon atoms.

167(new). The method according to claim 151, wherein the fatty acid ii) is selected from the group consisting of oleic acid, lauric acid, capric acid and caprylic acid.

168(new). The method according to claim 143, wherein the purity of monoglyceride i) is at least 90%.

169(new). The method according to claim 143, wherein the purity of monoglyceride i) is at least 95%.

170(new). The method according to claim 143, wherein the acyl group of the monoglyceride i) contains from 8 to 20 carbon atoms.

171(new). The method according to claim 143, wherein the acyl group of the monoglyceride i) contains from 14 to 20 carbon atoms.

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172(new). The method according to claim 143, wherein the monoglyceride i) is selected from the group consisting of mono-olein, monomyristate, mono laurate and mono caprate.

173(new). The method according to claim 143, wherein the acyl group of the fatty acid ii) contains from 8 to 20 carbon atoms.

174(new). The method according to claim 143, wherein the acyl group of the fatty acid ii) contains from 14 to 20 carbon atoms.

175(new). The method according to claim 143, wherein the fatty acid ii) is selected from the group consisting of oleic acid, lauric acid, capric acid and caprylic acid.

176(new). A method of immunizing a human or animal, the method comprising administering to a human or animal a vaccine composition comprising an adjuvant as defined in claim 143 and an immunogenic quantity of an antigen component.

177(new). The method according to claim 176, wherein the antigen component is capable of causing the formation of an immune response in a human or animal including marine animals.

178(new). The method according to claim 177, wherein the antigen component is selected from the group consisting of antigens from pathogenic and non-pathogenic bacteria, viruses, parasites and tumor cells.

179(new). The method according to claim 176, containing, in 100 g of the final vaccine composition:

from 0.01 to 90 g of the antigen component

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from 1 to 20 g of the monoglyceride i)
from 1 to 20 g of the fatty acid ii)
from 0.01 to 99 g of water
from 0.01 to 99 g of PBS or saline
and optionally one or more excipients.

180(new). The method according to claim 176, wherein the vaccine composition comprises additional pharmaceutical excipients selected from the group consisting of preservatives, osmotic pressure controlling agents, pH-controlling agents, organic solvents, enzyme inhibitors, water absorbing polymers, absorption promoters and anti-oxidative agents.

181(new). The method according to claim 176, wherein the vaccine composition is in a form suitable for parenteral or mucosal administration.

182(new). The method according to claim 181, wherein the vaccine composition is in a form suitable for administration to the mucosa of the nose, mouth, vagina, rectum or intestine.

183(new). The method according to claim 181, wherein the vaccine composition is in a form suitable for administration to the mucosa of the nose.

184(new). The method according to claim 176, wherein the antigen component is selected from the group consisting of diphtheria toxoid, influenza virus, and rotavirus.

185(new). The method according to claim 176, wherein the content of monoglyceride i) of the adjuvant is at least 90%.

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186(new). The method according to claim 176, wherein the content of monoglyceride i) of the adjuvant is at least 95%.

187(new). The method according to claim 176, wherein the acyl group of the monoglyceride i) of the adjuvant contains from 8 to 20 carbon atoms.

188(new). The method according to claim 176, wherein the acyl group of the monoglyceride i) of the adjuvant contains from 14 to 20 carbon atoms.

189(new). The method according to claim 176, wherein the monoglyceride i) is selected from the group consisting of mono-olein, monomyristate, mono laurate and mono caprate.

190(new). The method according to claim 176, wherein the acyl group of the fatty acid ii) of the adjuvant contains from 8 to 20 carbon atoms.

191(new). The method according to claim 176, wherein the acyl group of the fatty acid ii) of the adjuvant contains from 14 to 20 carbon atoms.

192(new). The method according to claim 176, wherein the fatty acid ii) is selected from the group consisting of oleic acid, lauric acid, capric acid and caprylic acid.

193(new). The method according to claim 142, wherein the monoglyceride i) is selected from the group consisting of mono-olein, monomyristate, mono laurate and mono caprate.